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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/777,552

02/12/2004

Daniel A. Hammer

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EXAMINER

SCHLIENTZ, LEAH H

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

04/07/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/777,552	Applicant(s) HAMMER ET AL.	
	Examiner Leah Schlientz	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/2/09.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 10, 12, 13, 15-23, 32-42, 46, 52, 55, 60, 62, 63, 65, 70-75, 78, 79 and 88-101 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 1,10,12-52,55,60,62-107,109-117,119-131,133-141,143-153,155-166,168-170 and 172-184.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 14,24-31,43-45,47-51,56-59,64,66-69,76,77,80-87,102-107,109-117,119-131,133-141,143-153,155-166,168-170 and 172-184.

DETAILED ACTION

Acknowledgement of Receipt

Applicant's Response, filed 2/2/2009, in reply to the Office Action mailed 9/3/2008, is acknowledged and has been entered. Claims 4-9 and 56-59 have been cancelled. Claims 1, 12-16, 22-25, 27-36, 39-43, 45, 47-52, 55, 60, 62-65, 67-69, 76, 78-81, 83-92, 97, 101-106, 109, 110, 113, 114, 116, 117, 119, 127, 133, 137, 138, 140, 141, 143, 150, 151, 155, 168 and 169 have been amended. Claims 1, 10, 12-52, 55, 60, 62-107, 109-117, 119-131, 133-141, 143-153, 155-166, 168-170 and 172-184 are pending, of which claims 14, 24-31, 43-45, 47-51, 56-59, 64, 66-69, 76, 77, 80-87, 102-107, 109-117, 119-131, 133-141, 143-153, 155-166, 168-170 and 172-184 are withdrawn from consideration at this time as being drawn to a non-elected invention. Claims 1, 10, 12, 13, 15-23, 32-42, 46, 52, 55, 60, 62, 63, 65, 70-75, 78, 79 and 88-101 are readable upon the elected invention and are examined herein on the merits for patentability.

Response to Arguments

Any rejection not reiterated herein has been WITHDRAWN.

Applicant's arguments, with respect to the rejection of claims 1, 10, 12, 13, 15-23, 32-42, 46, 52, 55, 60, 62, 63, 65, 70-75, 78, 79 and 88-101 under 35 USC 103(a) as being unpatentable over Klaveness (US 6,159,445) and Unger (US 6,123,923), in view

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of Lee (*Biotechnol. and Bioeng.*, 2001, 73, 135-145), in further view of Lin (*Chem. Eur. J.*, 1995, 1, p. 645 – 651), have been fully considered but they are not persuasive, for reasons set forth hereinbelow.

Applicant's arguments, with respect to the provisional rejection of claims 1, 10, 12, 13, 15-23, 32-42, 46, 52, 55, 60, 62, 63, 65, 70-75, 78, 79 and 88-101 on the ground of nonstatutory obviousness-type double patenting have been fully considered. The provisional rejection is maintained for reasons set forth in the previous Office Action.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 10, 12, 13, 15-23, 32-42, 46, 52, 55, 60, 63, 65, 70-75, 78, 79 and 88-101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klaveness (US 6,159,445) and Unger (US 6,123,923), in view of Lee (*Biotechnol. and Bioeng.*, 2001, 73, 135-145), in further view of Lin (*Chem. Eur. J.*, 1995, 1, p. 645 – 651), for reasons set forth in the previous Office Action.

Applicant argues on pages 32-34 of the Response that the Klaveness patent is alleged to disclose contrast agents having an absorption and/or emission in the 600 to 1300 nm range, noting that Klaveness teaches a laundry list encompassing a large number of compositions to be used in this function. Applicant asserts that Klaveness

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does not teach two porphyrin moieties linked by an unsaturated hydrocarbon bridge much less a moiety that exhibits an integral oscillator strength that is greater than the oscillator strength manifest by either one of the porphyrin moieties individually.

Applicant asserts that Klaveness is also defective concerning the instant amphiphilic copolymers that have at least one hydrophilic polymer bonded to at least one hydrophobic polymer, and that there is an extensive list of possibilities of carrier for the contrast agent, such that it would not be obvious to select amphiphilic block copolymers of EP 166596, and that there is no guidance to pick and choose the particular combinations that would allow one to arrive at the claimed invention. Applicant asserts that no element of any claim under consideration can clearly be found in the Klaveness patent. With regard to the Unger patent, Applicant argues that with regard to the emissive agent, no porphyrin moieties are disclosed which include those linked by a hydrocarbon bridge, and that synthetic vessel forming materials are selected from a large list of possibilities where no preference is stated for this possibility. Applicant further argues that the Lee article is used to provide a disclosure of amphiphilic block copolymer to assert favorable properties, and that the Lin article is asserted to teach certain linked porphyrins. Applicant asserts that all elements from the teaching of the primary reference are replaced by components from additionally cited art or selected from extensive list from within the primary patent, and that based on the significant changes to and picking and choosing from the disclosures of Klaveness and Unger patents, it seems that the instant invention can only be derived through the use of impermissible hindsight based on Applicant's blueprint.

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This is not found to be persuasive. With regard to the carrier material in the Klaveness and Unger patents, Klaveness and Unger provide a general teaching for the use of amphiphilic block copolymers as carrier vesicles for emissive agents and their use as optical probes. Patents are relevant as prior art for all they contain. See MPEP 2123 (1). "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), *cert. denied*, 493 U.S. 975 (1989). See also *Upsher-Smith Labs. v. Pamlab, LLC*, 412 F.3d 1319, 1323, 75 USPQ2d 1213, 1215 (Fed. Cir. 2005). With regard to the porphyrin moiety, Klaveness teaches that a variety of fluorophore compounds may be incorporated, and clearly teaches the desirable spectral features of suitable fluorophores and reasoning for why such spectral features are important in liposomal or polymeric vesicles for optical imaging. Lin teaches compounds meeting these spectral features, and teaches that they may be used in optical probes. One of ordinary skill would have been able to substitute one known emissive agent having desirable optical properties for another with the expected result of achieving optical imaging employing a fluorescence emitting polymeric membrane. In response to applicant's argument that the examiner's conclusion of obviousness is

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based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicant further argues that there is nothing in the Lin article that suggests that the compositions would be an improvement over the moieties used in the primary references, and that the Lin article teaches nothing about the enhanced property that the compositions exhibit an integral oscillator strength that is greater than the oscillator strengths of the monomers, which might make the multiporphyrins of the instant claims to be attractive for use in the methods of the Unger patent.

In response to applicant's argument that Lin does not recognize the benefit of enhanced oscillator strength, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Since the compounds of Lin are structurally identical to those claimed, they would inherently possess the functional property of integral oscillator strength that is greater than the oscillator strengths of the porphyrin monomers.

New Grounds for Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10, 12-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are dependent upon claim 2, which is a cancelled claim. Therefore the metes and bounds of the claims are not clearly set forth and the scope of the invention cannot be fully ascertained.

Conclusion

No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later

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than SIX MONTHS from the date of this final action. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leah Schlientz whose telephone number is 571-272-9928. The examiner can normally be reached on Monday - Friday 8 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

LHS